UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA NEWPORT NEWS DIVISION

ARTHUR STILIANOS 2727 Charmaine Drive Hayes, VA 23072-4426 Plaintiff,	)	
v.	)	**Civil Action No.:**
AETNA LIFE INSURANCE COMPANY, 151 Farmington Avenue Hartford, CT 06156 SERVE: Aetna Life Insurance Company c/o C T Corporation 4701 Cox Rd Ste 285, Glen Allen, VA, 23060 – 6808	)	
OCEAN SHIP MANAGEMENT, INC. HEALTH BENEFIT PLAN, 16211 Park Ten Place Houston, TX 77084 SERVE: Ocean Ship Management, Inc. 16211 PARK TEN PLACE Houston, TX 77084 Defendants.	)	

COMPLAINT

Plaintiff, ARTHUR STILIANOS, submits this Complaint against Defendants AETNA LIFE INSURANCE COMPANY and the OCEAN SHIP MANAGEMENT, INC. HEALTH BENEFIT PLAN and respectfully states as follows:

The Parties

1. Plaintiff Arthur Stilianos is and was at all relevant times a resident of the Commonwealth of Virginia.

2. Plaintiff has resided at all relevant times in Gloucester County, Virginia.

3. The claims at issue were specifically administered in this judicial district by Defendant Aetna Life Insurance Company (hereafter "Aetna").

4. Aetna is a corporation with its principal place of business in the State of Connecticut, and is authorized to transact, and is transacting business in this judicial district of the Eastern District of Virginia, and can be found in the Eastern District of Virginia.

5. Plaintiff was entitled to health care benefits under a self-funded group employee welfare benefit plan regulated by ERISA as a result of his employment.

6. The name of the Plan was "Ocean Ship Management, Inc." Health Benefit Plan (Member ID#: 621M88132) (hereafter referred to as "the Plan"). The Ocean Ship Plan funds the payment of benefits under this Plan.

7. Attached as Exhibit A is a true and correct copy of Plaintiff's Certificate of Coverage for the Plan.

8. Defendant Ocean Ship Management, Inc. Health Benefit Plan (hereafter "Ocean Ship") is the sponsor and administrator of the Plan.

9. Ocean Ship is a corporation with its principal place of business in the state of Texas.

10. Payment for the medical benefits under the Plan and decisions made regarding what medical benefits will be provided are determined by Aetna.

11. The medical claims at issue herein were specifically administered in this judicial district, such that venue is expressly proper in this judicial district pursuant to 29 U.S.C. § 1132€(2) (special venue rules applicable to ERISA actions).

Jurisdiction

12. This action is brought under 29 U.S.C. §§ 1132(a), (e), (f) and (g) of the Employee Retirement Income Security Act of 1974 (hereinafter "ERISA") as it involves a claim by Plaintiff for employee benefits under an employee benefit plan regulated and governed by ERISA.

13. Jurisdiction is predicated under these code sections as well as 28 U.S.C. § 1331, as this action involves a federal question.

14. This action is brought for the purpose of obtaining benefits under the terms of an employee benefit plan, enforcing Plaintiff's rights under the terms of an employee benefit plan, and to clarify Plaintiff's rights to future benefits under the employee benefit plan.

15. Plaintiff seeks relief, including but not limited to payment of benefits, prejudgment and post-judgment interest, and attorneys' fees and costs.

Introduction and Background of Proton Beam Radiation Therapy

16. Proton beam radiation therapy ("PBRT" or "proton therapy") has been recognized for decades by the medical community as an established, medically appropriate treatment for cancer, including prostate cancer.

17. The first hospital-based proton-beam center in the United States was at the Loma Linda University Medical Center, which began operation in 1990.

18. Through local coverage determinations or the guidelines adopted by various Medicare Advantage organizations (MAOs), Medicare generally covers PBRT for prostate cancer.

19. PBRT is the most effective form of radiation therapy for many types of cancer.

20. PBRT destroys cancer cells by preventing them from dividing and growing, like conventional X-ray radiation.

21. The difference between PBRT and conventional X-ray radiation is that protons deposit much of their radiation directly in the tumor and then stop.

22. That allows patients to receive higher doses, which can be more effective, while reducing damage to healthy tissues that surround the tumor.

23. The physical properties of protons are different from the physical properties of X-rays.

24. Protons are large, positively charged sub-atomic particles that penetrate matter to a finite depth.

25. X-rays are electromagnetic radiation that penetrate completely through tissue.

26. Protons can be conformed to release much of their energy at precise depths so they can target tumors inside the body, depositing much of their radiation exactly at the tumor site.

27. X-rays release their maximum dose of radiation quickly after penetrating the skin, damaging healthy tissue and organs on their way to the tumor and again as they pass through the body beyond the tumor.

28. The goal of treatment is to deliver the proper dose of radiation to the tumor while limiting the dose received by the surrounding healthy tissue.

29. To deposit the proper amount of energy into the tumor, X-rays must irradiate much of the healthy tissue in front of it, known as an "entrance dose," and then continue to penetrate through the tumor and irradiate much of the healthy tissue behind it, known as an "exit dose."

30. To deliver the proper dose to a tumor, a radiation oncologist must "work around" the tumor by using multiple X-ray beams, delivering the highest dose where the beams intersect, but delivering low to medium "entrance" and "exit" doses to surrounding healthy tissue.

31. In contrast, protons enter the patient at a low dose, then, at a precise depth, they deliver a large burst of energy.

32. Immediately after this burst, they stop completely.

33. To treat the entire tumor, additional protons are sent in at lower doses.

34. In this way, protons completely irradiate the tumor while limiting the dose to the nearby healthy tissue.

35. Proton treatment delivers a dose in a more accurate way, a more efficient way, and spares more of the surrounding healthy tissue.

36. Since protons have a low "entrance dose" and essentially no "exit dose," the volume of normal tissue receiving radiation with PBRT is typically reduced by a factor of 2-3 when compared to even the most modern X-ray treatment plan.

37. Proton radiation therapy offers reduced toxicity over intensity-modulated therapy (IMRT) in patients under the age of 65 with prostate cancer.

38. Proton therapy is the most effective form of treatment for prostate cancer because it minimizes the radiation dose to vital bodily organs and functions, such as the gastrointestinal system or urinary tract.

39. Many respected cancer facilities and providers, including but not limited to, MD Anderson at the University of Texas, Harvard Medical School/Massachusetts General Hospital, Northwestern University, Baptist Hospital's Miami Cancer Institute, Loma Linda University, University of Florida, University of Maryland, Mayo Clinic, Emory University, Case Western Reserve University, Washington University in St. Louis, University of Washington, New York Proton Center, and the Texas Center for Proton Therapy recommend and use PBRT on a regular basis.

40. The medical community has found proton beam therapy radiation treatment to be a generally accepted standard of medical practice for the treatment of prostate cancer.

41. Other insurers, including Medicare, cover PBRT as a safe and effective prostate cancer treatment that is not "investigational."

42. There is overwhelming evidence that PBRT is safe and effective.

43. PBRT is a generally accepted standard of medical practice for the treatment of cancer, including breast cancer, within the medical community.

44. PBRT has been around and well-accepted for over 30 years.

45. The Food and Drug Administration ("FDA") approved PBRT in 1988 with the following specific statement of indications for intended use: "The [Proton Therapy System] is a medical device designed to produce and deliver proton beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation."

46. The American Society for Radiation Oncology (ASTRO), the National Comprehensive Cancer Network (NCCN), and other nationally-recognized medical organizations have validated the safety and effectiveness of PBRT.

47. Numerous peer-reviewed studies have validated the safety and effectiveness of PBRT.

48. There is randomized Level I dual-institutional trial evidence to support the use of proton therapy for prostate cancer.

49. This also sets proton therapy apart from conventional X-ray radiation, as historically the radiation oncology field has not performed many randomized trials testing whether or not one technology is better than another.

50. Because radiation therapy is based on well understood principles of physics, a randomized trial is not necessary to know whether or not more energy will be deposited into healthy tissue with X-rays than with proton therapy.

51. That X-rays will irradiate more surrounding healthy tissue than proton therapy is a scientific fact.

52. Instead, the field is interested in whether or not more energy can be delivered to the tumor and less to healthy tissue.

53. In contrast, there is no randomized data or prospective data to support the use of X-ray radiation to treat prostate cancer, the default fallback to which Aetna has forced its subscribers to resort by virtue of its systematic denial of PBRT for the treatment of prostate cancer.

54. For example, the PROG 95-09 study published in the Journal of the American Medical Association (JAMA) in 2008—*over 12 years ago*—demonstrated that safe dose escalation is achievable with proton therapy.

55. The PROG 95-09 study is randomized Level I evidence based on data from Massachusetts General Hospital in Boston, Massachusetts, and Loma Linda Medical Center in Loma Linda, California.

56. In this dose escalation study, patients with early prostate cancer were assigned to receive either standard dose or high dose radiation.

57. In the PROG 95-09 study, unlike other dose escalation studies, even patients in the standard dose group received a combination of X-ray radiation and proton therapy, as opposed to X-ray radiation alone.

58. When compared to three other dose escalation studies in which patients did not receive proton therapy, the PROG 95-09 study had the best control rates and the least side effects.

59. By using proton therapy one is able to safely treat the tumor with a higher dose of radiation, which leads to a higher probability of killing the tumor and to fewer side effects and complications.

60. The PROG 95-09 study reports patient-reported quality-of-life outcomes at a median of 9.4 years after treatment which is the longest published follow-up after radiation therapy for prostate cancer.

61. The study was the first time physicians were able to dose escalate in treating prostate cancer without an increase in toxicity.

62. Long-term data from the PROG 95-09 study were published in March 2010 in the Journal of Clinical Oncology.

63. With a median follow up of 8.9 years, the high-dose group was exhibiting a statistically significant improvement in biochemical disease-free survival.

64. Critically, this improved outcome was achieved without increasing significant long-term genitourinary or gastrointestinal toxicity.

65. This shows that a radiation oncologist can use proton therapy to dose-escalate and improve disease control without increasing long-term patient side effects.

66. In contrast, dose escalation studies relying on X-ray radiation have reported that increasing the radiation dose was associated with substantial increased risk of late gastrointestinal toxicity.

67. The PROG 95-09 study demonstrates that proton therapy is a superior treatment for prostate cancer.

68. Patient-reported outcomes are the most sensitive and valid measures of treatment-related morbidity.

69. The March 2010 results of the PROG 95-09 study showed that radiation at the higher doses was not associated with increased patient-reported, long-term, treatment-related urinary, bowel, or sexual dysfunction or related quality-of-life outcomes.

70. Furthermore, the PROG 95-09 study resulted in superior tumor control at 5 years and lower rates of Grade 2 and Grade 3 gastrointestinal toxicity than other randomized studies relying on conventional X-ray radiation rather than proton therapy.

71. The PROG 95-09 study represents a randomized trial with follow-up often years showing that proton beam therapy is associated with equivalent or superior long-term outcomes.

72. IMRT previously was the most common treatment for localized prostate cancer between 2000 and 2010, but newer radiation techniques have improved on IMRT.

73. "PBRT decreases low-dose radiation exposure to uninvolved organs, which potentially translates into lower risks of treatment toxicity and secondary malignancy," wrote the authors of a recent study led by Benjamin D. Smith, MD, of the University of Texas MD Anderson Cancer Center in Houston. *Journal of Clinical Oncology* 36, no, 18 (published online March 21, 2018).

74. This study surveyed the cases of a total of 693 patients who received proton radiation between 2008 and 2015 and were matched to 3,465 IMRT patients.

75. The PBRT patients had a lower risk of composite urinary toxicity at 2 years, at a rate of 33% compared with 42%.

76. Erectile dysfunction was also less likely with PBRT, at a rate of 21% at 2 years compared with 28%.

77. The study also observes that the 2-year mean complication cost was lower with PBRT ($1,737 vs. $2,730).

78. In May 2016, the University of Florida Health PBRT Institute published a study in the *International Journal of Radiation Oncology Biology Physics* that reports 5-year outcomes of more than 1,300 prostate cancer patients treated at the Institute from 2006 to 2010.

79. The study shows that PBRT is a highly effective treatment for low-risk, intermediate-risk, and high-risk prostate cancer.

80. The study also reported a low rate of serious side effects. Five-year biochemical results, toxicity, and patient-reported quality of life after delivery of dose-escalated image guided PBRT for prostate cancer. *Int J Radiat Oncol Biol Phys* 2016; 95:422-434.

81. The medical community has found PBRT treatment to be both medically necessary and a superior form of treatment than established alternative treatments for the treatment of prostate cancer.

82. Most importantly, Plaintiff's treating provider, Dr. Christopher Sinesi of the Hampton University Proton Therapy Institute ("HUPTI"), found PBRT to be the best form of treatment for Plaintiff.

Plaintiff Specific Facts

83. Plaintiff incorporates by reference all preceding paragraphs as though fully set forth herein.

84. Plaintiff is a 59-year-old man who was diagnosed with high-risk prostate cancer in 2017.

85. Plaintiff sought care and treatment at the Hampton University Proton Therapy Institute ("HUPTI").

86. In April of 2019 it was recommended that Plaintiff be treated with PBRT.

87. Plaintiff's doctors determined that PBRT was the best course of treatment for Plaintiff.

88. Plaintiff's doctors concluded that PBRT was medically necessary for Plaintiff because PBRT, as opposed to Intensity-Modulated radiation therapy (IMRT), greatly reduces the risk of creating a radiation-induced malignancy.

89. By July 2019, Plaintiff's prostate-specific antigen ("PSA") level was 13.12, which is an extremely high level.

90. On May 2, 2019, Aetna denied Plaintiff's request for PBRT on the following grounds:

> We used the Clinical Policy Bulletin (CPB): Proton Beam and Neutron Beam Radiotherapy. Based on CPB criteria and the information we have, . . . [m]edical studies do not prove that this procedure is better than and as safe as other radiation treatment for prostate cancer . . . there is no clear evidence that proton beam therapy for prostate cancer offers any clinical advantage over other forms of definitive radiation therapy . . . the plan does not cover experiment or investigational services except under certain conditions.

91. On May 24, 2019, Plaintiff's treating doctor, Dr. Sinesi, appealed this denial to Aetna, stating that:

> Proton therapy is the preferred treatment modality for the patient over IMRT, due to excellent disease control and the ability to minimize the radiation dose to the rectum, bladder, and penile bulb. A recent report of using proton therapy for prostate cancer among 1327 men demonstrated a 5-year biochemical control of 99% for low risk, 94% for intermediate risk, and 75% for high risk prostate cancer. (citation omitted). A recent comparative effectiveness study demonstrated significantly fewer patients developing moderate or severe rectal urgency and rectal frequency following proton therapy compared with IMRT (citation omitted). This reduction in bowel urgency and frequency is attributed to the reduction of the bowel receiving moderate doses of radiation 30-50 Gy (citation omitted). Additionally, the dosimetric advantages of proton therapy with less integral radiation dose has been shown to reduce the risk of potential secondary cancers from radiation compared with photon radiation. (citation omitted)
>
> Mr. Stilianos has an additional complicating factor of hip replacement surgery. The presence of a metal prosthesis in his hip degrades IMRT treatment significantly. We have a special technique for treating prostate cancer with proton beam radiation in patients who have a metal prostatic hip with minimal additional exposure to critical structures including the rectum. In addition, Mr. Stilianos will be treated as part of the National PCG Proton Registry. The current ASTRO Guidelines for the appropriate use of proton beam radiation recommend that patients with prostate cancer be treated with protons as part of a national protocol or registry.

92. Despite these compelling reasons for approving Plaintiff's request for PBRT, Aetna denied the appeal with a letter dated, "May 24, 2019," notice of which was not provided to HUPTI until May 31, 2019 and was not received by HUPTI until June 6, 2019.

93. On May 31, 2019, HUPTI submitted a second level appeal to Aetna, and on the same day HUPTI received a call back stating that Aetna's decision to deny Plaintiff's request for PBRT was upheld.

94. No physical letter from Aetna regarding this second level appeal denial was ever received by HUPTI or by Plaintiff.

95. On October 14, 2019, Aetna sent a denial letter denying Plaintiff's pre-service claim for PBRT on the grounds that: "The plan does not cover services that are not medically necessary."

96. Plaintiff underwent 44 rounds of PBRT at HUPT starting on July 18, 2019 and his treatment was completed on September 18, 2019.

97. On April 6, 2020, Plaintiff appealed Aetna's denial.

98. On May 7, 2020, Aetna upheld its denial, relying on its Clinical Policy Bulletin Number: 0270 "Proton Beam, Neutron Beam, and Carbon Ion Radiotherapy" ("PBRT Clinical Policy Bulletin"), on the following grounds: "We do not cover proton beam radiotherapy for individuals with localized prostate cancer. Medical studies have not proven it to be more effective than other radiotherapy modalities for this indication."

99. On July 2, 2020 Plaintiff appealed Aetna's May 7 denial.

100. On August 1, 2020 Aetna upheld its denial of Plaintiff's second level appeal stating:

> Based on our review of the information given, Aetna's Clinical Policy Bulletin (CPB) # 0270, Proton Beam and Neutron Beam Radiotherapy, review date 05/09/2018, and Clinical Policy Bulletin (CPB) # 0270, Proton Beam and Neutron Beam Radiotherapy, review date 07/29/2019, we are upholding the prior denial of coverage. The basis of this determination is that you did not meet the criteria. Our review found that you have a diagnosis of localized prostate cancer. Aetna considers proton beam radiotherapy for treatment of prostate cancer not medically necessary for individuals with localized prostate cancer because it has not been proven to be more effective than other radiotherapy modalities for

this indication. Therefore, criteria are not met, and the previous denial of coverage is upheld.

101. In all pre-service and post-service appeals, Plaintiff and his treating providers submitted extensive medical literature and analysis showing that proton therapy results in superior outcomes and reduced long-term side effects as compared with IMRT.

102. Dr. Sinesi and Plaintiff's appeal submissions to Aetna make clear that the medical community has found that in Plaintiff's case PBRT is both medically necessary and a superior form of treatment, citing to numerous sources of established peer-reviewed literature proving this claim.

103. For example, Dr. Sinesi's appeal submission on Plaintiff's behalf to Aetna cited to the following sources of established peer-reviewed literature proving the claim that PBRT is both medically necessary and a superior form of treatment for prostate cancer over IMRT:

- Hoppe B, et al., Comparative Effectiveness Study of Patient reported Outcomes after Proton Therapy or Intensity-modulated radiotherapy for Prostate Cancer. *Cancer*. 2014; 20:1076-82 (a comparative effectiveness study demonstrating that significantly fewer patients developed moderate or severe rectal urgency and rectal frequency following proton therapy compared with IMRT.)

- Fontenot J.D., et al., Risk of secondary malignant neoplasms from proton therapy and intensity-modulated x-ray therapy for early-stage prostate cancer. INT J RADIAT ONCOL BIOL PHYS. 2009 Jun 1; 74(2):616-22. (concluding that the dosimetric advantages of proton therapy with less integral radiation dose reduces the risk of potential secondary cancers from radiation compared with photon radiation.)

104. In summary, Plaintiff's pre-service and post-service appeals to Aetna contained citations to and physical copies of at least ten peer-reviewed scientific studies,

published between 2006 and 2019, all conclusively finding PBRT to be both medically necessary and a superior form of treatment than established alternative treatments (like IMRT) for the treatment of prostate cancer.

105. In its responses to Plaintiff's appeals, Aetna failed to reference the extensive medical literature demonstrating the advantages of proton therapy over IMRT, just as it failed to reference any purported medical literature in its PBRT Clinical Policy Bulletin supporting its position to deny PBRT.

106. Following the denial of benefits under the Plan, Plaintiff exhausted all administrative remedies required under ERISA.

107. Plaintiff performed all duties and obligations on his part to be performed under his contract of insurance at all times.

Relevant Plan Definitions

108. Plaintiff sought coverage for PBRT under the Plan, which includes a list of "Exclusions," which are deemed to be services that are not covered under the Plan.

109. One such Exclusion is for services deemed "Experimental or Investigational" (the "E/I Exclusion"), where "Experimental or Investigational" is defined as:

> A drug, device, procedure, or treatment that is found to be experimental or investigational because:
>
> - There is not enough outcome data available from controlled clinical trials published in the peer- reviewed literature to validate its safety and effectiveness for the illness or injury involved
> - The needed approval by the FDA has not been given for marketing
> - A national medical or dental society or regulatory agency has stated in writing that it is experimental or investigational or suitable mainly for research purposes

- It is the subject of a Phase I, Phase II or the experimental or research arm of a Phase III clinical trial. These terms have the meanings given by regulations and other official actions and publications of the FDA and Department of Health and Human Services
- Written protocols or a written consent form used by a facility provider state that it is experimental or investigational.

110. Radiation therapy is a procedure, and therefore, is not subject to FDA regulation.

111. The accelerators and other equipment used to generate and deliver PBRT are regulated by the FDA.

112. On February 22, 1988, the FDA approved the Proton Therapy System, and designated it as a Class II Device for radiological treatment.

113. This classification was codified at 21 C.F.R. § 892.5050 and describes the Proton Therapy System as a "device that produces by acceleration high energy charged particles (e.g., electrons and protons) intended for use in radiation therapy."

114. Thus, at least as of February 22, 1988, PBRT no longer fit within the E/I Exclusion to the Plan.

115. PBRT has long been recognized as an established, medically appropriate treatment for the treatment of cancer, including prostate cancer.

116. The Plan contains an exclusion for services that are not "Medically Necessary" where the Plan defines "Medically Necessary" as follows:

> Health care services that a provider exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- In accordance with generally accepted standards of medical practice.
- Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease.
- Not primarily for the convenience of the patient, physician, or other health care provider.
- Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

"Generally accepted standards of medical practice means": Standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community.

117. Proton therapy for prostate cancer is medically necessary and is not excluded under the exclusion for services that are not medically necessary.

118. The rationales articulated by Aetna in its pre-service and post-service appeal denials of Plaintiff's claims for PBRT amount to the following: "Medical studies do not prove that this procedure ***is better than and as safe as other radiation treatment for prostate cancer . . .*** there is no clear evidence that proton beam therapy for prostate cancer offers ***any clinical advantage over other forms of definitive radiation therapy***." (emphasis added)

119. This rationale plainly ignores the overwhelming peer-reviewed medical literature that concludes that PBRT is safe, effective, and a superior form of treatment for prostate cancer.

Aetna's Adjudication of Plaintiff's Claims for PBRT Violate State Law

120. Virginia law expressly prohibits health benefit plans providing coverage for cancer therapy from holding PBRT to a higher standard of clinical evidence in medical

policy benefit coverage than the health plan requires for coverage of any other radiation therapy treatment. Code of Virginia § 38.2-3407.14:1.

121. The statute states that "each policy, contract, or plan issued or provided by a carrier that provides coverage for cancer therapy shall not hold proton radiation therapy to a higher standard of clinical evidence for decisions regarding coverage under the policy, contract, or plan than is applied for decisions regarding coverage of other types of radiation therapy treatment."

122. The rationales articulated in Aetna's pre-service and post-service denials of Plaintiff's claims for PBRT are in direct violation of Virginia law.

Aetna's PBRT Clinical Policy

123. Aetna drafted and implemented the PBRT Clinical Policy Bulletin, which at the time Aetna applied it to Plaintiff's requests for PBRT was most recently reviewed on March 14, 2019.

124. Aetna's PBRT Clinical Policy Bulletin was based on outdated medical evidence and ignored accepted medical peer-reviewed evidence that PBRT is safe and effective for the treatment of cancer.

125. The unreasonableness of the PBRT Clinical Policy is illustrated by the fact that Aetna considers PBRT "experimental and investigational" for most types of cancers, including prostate cancer, in "adults (over age 21) . . . because its effectiveness for these indications has not been established" while on the other hand Aetna considers PBRT "medically necessary" to treat all "[m]alignancies in children (21 years of age and younger)," as well as certain listed types of tumors.

126. Aetna's PBRT Clinical Policy Bulletin does not consider PBRT "experimental and investigational" when treating children (21 years of age and younger) and approves PBRT for these patients.

127. There are no medical studies that support a conclusion that PBRT would be a proven, safe, and effective treatment for the same cancer in one age group but not the other.

128. Aetna employs the PBRT Clinical Policy Bulletin as part of its prior authorization review and adjudication of members and beneficiaries' claims to deny claims for coverage of PBRT as "experimental or investigational" or not "medically necessary" without ever engaging in any reasonable review of clinical records prior to rendering the determination of coverage.

129. Aetna drafts, adopts, and implements its PBRT Clinical Policy Bulletin—as it did here with respect to Plaintiff's requests and claims for PBRT—by relying upon outdated medical evidence, by ignoring contemporary medical evidence, and by taking a coverage position that plainly contradicts the standard of care in the medical community.

130. Aetna's application of its PBRT Clinical Policy Bulletin to Plaintiff's requests and claims for PBRT is an improper substitute to Aetna's legal obligation to conduct an adequate, full, and fair review of member-submitted clinical records like Plaintiff's.

131. Aetna did not provide Plaintiff with a full and fair review of his clinical records by appropriate medical directors (who have experience or training in the context

of radiation oncology or who are board certified in the requisite medical specialty) prior to rendering its coverage determinations.

132. It is readily apparent that at no point during the claims and appeals processes that Aetna's medical reviewers considered any of the factors specific to Plaintiff's diagnosis but rather applied its blanket policy of denying proton therapy for prostate cancer.

133. It is also apparent that Aetna never addressed how its PBRT Clinical Policy Bulletin, with its outdated references, could possibly have reasonably provided a fair snapshot of whether PBRT was considered experimental/investigational in 2019, which is the relevant time period related to Plaintiff's requests for PBRT.

134. Aetna's reliance on its PBRT Clinical Policy Bulletin is merely a way for Aetna to categorically deny prior authorization requests and claims for reimbursement for PBRT to treat most cancers, including prostate cancer.

FIRST CAUSE OF ACTION
FOR DENIAL OF PLAN BENEFITS UNDER ERISA

135. Plaintiff incorporates by reference the foregoing paragraphs as though fully set forth herein.

136. Plaintiff was covered under the Plan at all relevant times.

137. Plaintiff's requested and performed treatment was covered under this group policy as it was medically necessary, constituted appropriate medical treatment, and was not experimental, investigational, or unproven.

138. Defendants wrongfully denied Plaintiff's claim for PBRT in the following respects:

(a) Wrongfully concluding PBRT was excluded as experimental or investigational, or not medically necessary, when in fact PBRT is a mainstream treatment which has been performed by reputable physicians for decades;

(b) Failure to provide prompt and reasonable explanations of the bases relied on under the terms of the plan documents, in relation to the applicable facts and plan provisions, for the denial of Plaintiff's requests;

(c) After Plaintiff's claims were denied in whole or in part, failure to adequately describe to Plaintiff any additional material or information necessary for Plaintiff to perfect his claim along with an explanation of why such material is or was necessary;

(d) Failure to properly and adequately investigate the merits of Plaintiff's request and/or consider the information provided by Plaintiff; and

(e) Failure to consider the overwhelming medical evidence which showed that the requested treatment was medically necessary, safe, effective, and not investigational.

139. Plaintiff is prepared to amend to allege that, if he confirms in discovery, Defendants wrongfully denied the claim for benefits by other acts or omissions.

140. Following the denial of the claims for benefits under the Plan, Plaintiff exhausted all administrative remedies required under ERISA, and performed all duties and obligations on his part to be performed.

141. As a proximate result of the denial of benefits due Plaintiff, Plaintiff has been irreparably damaged.

142. Plaintiff has been denied medically necessary treatment and left with a substantial sum of money to be paid by him out-of-pocket.

143. As a further direct and proximate result of this improper determination regarding the medical claims, Plaintiff, in pursuing this action, has been required to incur attorneys' costs and fees.

144. Pursuant to 29 U.S.C. § 1132(g)(1), Plaintiff is entitled to have such attorneys' fees and costs paid by Defendants.

145. Due to the wrongful conduct of Defendants, Plaintiff is entitled to enforce his rights under the terms of the Plan and to clarify his rights to future benefits under the terms of the Plan.

SECOND CAUSE OF ACTION FOR EQUITABLE RELIEF

146. Plaintiff incorporates by reference the foregoing paragraphs as though fully set forth herein.

147. As a direct and proximate result of the failure of the Defendants to pay claims for benefits, and the resulting injuries and damages sustained by Plaintiff as alleged herein, Plaintiff is entitled to and hereby requests that this Court grant Plaintiff the following relief pursuant to 29 U.S.C. § 1132(a)(1)(B):

(a) Restitution of all past benefits due to Plaintiff, plus prejudgment and post-judgment interest at the lawful rate; and

(b) Such other and further relief as the Court deems necessary and proper to protect the interests of Plaintiff under the Plan.

Request for Relief

Wherefore, Plaintiff prays for judgment against Defendants as follows:

1. Payment of health benefits due to Plaintiff under the Plan;

2. Pursuant to 29 U.S.C. § 1132(g), payment of all costs and attorneys' fees incurred in pursuing this action;

3. Payment of prejudgment and post-judgment interest as allowed for under ERISA; and

4. For such other and further relief as the Court deems just and proper.

Dated: January 14, 2020

Respectfully submitted,

ARTHUR STILIANOS

/s/ *Mikhael D. Charnoff*

Mikhael D. Charnoff, VSB No. 43929
PERRY CHARNOFF PLLC
1010 N. Glebe Road, Suite 310
Arlington, VA 22201
Tel: 703-291-6650
Fax: 703-563-6692
mike@perrycharnoff.com